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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/694,033
Filing Date: October 27, 2003
Appellant(s): BERG ET AL.

MAILED
JAN 10 2008
GROUP 1600

Michael Goltry
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 16 October 2007 appealing from the Office action mailed 18 May 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's brief presents arguments relating to the duplicity of claims. Specifically, a duplicate claim warning was made over claims 77-83, as being substantial duplicates of claims 70-76, over claim 84, as being a substantial duplicate of claims 74 and 81, and over claim 86, as being a substantial duplicate of claims 76 and 83. This issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection of claims 70-87 under 35 USC 102(b) as being anticipated by Dati et al (Seminars in Thrombosis and Hemostasis, 1998).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

(a) Wintrobe, M.M. et al, ed. "Approach to Patients with Bleeding Disorders." In: Clinical Hematology, 7th edition (Philadelphia, Lea & Febiger, 1974). pp. 1048-1070. RB 145 .W73.

(b) Sorensen et al, "Markers of Coagulation and Fibrinolysis After Fractures of the Lower Extremities" Thrombosis Research, vol. 65, no. 4/5 (1992), pp. 479-486.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Applicants' claim 70 is interpreted as being directed to an ex vivo diagnostic method, comprising the steps of: (i) performing a mental step of identifying conditions that cause a low coagulation response in blood; (ii) providing a blood sample from a subject; (iii) providing multiple blood tests, wherein each test can identify a low coagulation response level in blood; (iv) performing each of said blood tests on said blood sample; and if at least two of said blood tests identify an abnormal coagulation response in said blood sample, then (v) using the at least two blood tests which identified the abnormal coagulation responses to assist in diagnosing the subject with one of the conditions identified in step (i).

Claim 77 is the same as claim 70, except it only requires identification of a condition (singular) that causes a low coagulation response in blood in step (i). Dependent claims 72-76 and 79-83 define the multiple blood tests to be performed on the blood sample. Dependent claims 71 and 78 require multiple blood samples to be provided, and for the method to be carried out on each of the blood samples.

Claim 84 is substantially the same as claim 70, but specifies the blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation. Claim 84 also requires a step of obtaining a result for each of the blood tests and observing the results.

Claim 86 is the same as claim 84, except it only requires identification of a condition (singular) that causes a low coagulation response level in blood. Dependent claims 85 and 87 require multiple blood samples to be provided, and for the method to be carried out on each of the blood samples.

Claims 70-72, 74-79 and 81-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Wintrobe et al (Clinical Hematology, 1974).

Wintrobe et al disclose standard laboratory blood tests for evaluating hematostasis and blood coagulation in bleeding patients, provide guidance on how to interpret results of each of the various laboratory blood tests, and disclose conditions which may be the cause of any abnormal results obtained by the various laboratory blood tests.

Initially it is noted that conditions which cause a low coagulation response in blood were long known in the art; therefore the step of 'identifying' such conditions is inherently satisfied based on the state of the art. However, as further evidence, it is noted that both Tables 33-2 (Pg. 1050) and 33-3 (Pg. 1063) disclose various blood conditions, including those which cause a low coagulation response in blood (e.g. thrombocytopenia, thrombasthenia, hemophilia, von Willebrand's disease, and afibrinogenemia). Disclosure of such disorders is considered to be evidence of the mental step of 'identifying conditions that

cause a low coagulation response in blood'. Similarly, blood tests for which can identify low coagulation response in blood were long known in the art. However, again, Wintrobe et al do specifically disclose various blood tests which may be performed on a blood sample to test for the various blood conditions mentioned above. The various blood tests are discussed in detail on pages 1049-1062, and are also found in Table 33-3 (Pg. 1063) and Fig. 33-7 (Pg. 1066). Disclosure of such blood tests is considered to read on the step of 'providing different blood tests that are each for identifying low coagulation response in blood'.

To study the patients, Wintrobe et al state four 'primary' screening tests should be carried out, the primary screening tests including platelet count, bleeding time, partial thromboplastin time, and plasma prothrombin time (See Pg 1062, col. 2). It is submitted that these four primary screening tests read on 'different blood tests that are each for identifying low coagulation response in blood'. It is further submitted that one of ordinary skill in the art will recognize that in carrying out blood tests, a blood sample is necessarily taken from the patients, the selected tests are run on each of the blood samples, a result is obtained from each test, and the results are observed; therefore carrying out the four primary screening tests is considered to inherently read on the steps of 'providing a blood sample from one or more patients, performing each of the different blood tests on the blood sample, obtaining a result from each of the tests and observing the results'. At Table 33-3 Wintrobe et al provide guidance on how to interpret abnormal results test results from one or more of the four primary screening tests to arrive at a presumptive diagnosis. This disclosure of interpreting abnormal results to arrive at a presumptive diagnosis is considered to read on the step of 'using the blood tests to assist in diagnosing the subject with one or more of the conditions'. It is submitted the disclosed method of carrying out the primary screening tests, by itself, anticipates at least claims 70, 71, 77 and 78, as these claims only require 'different blood tests' which an identify low coagulation response in blood, and the four 'primary' screening tests read on such.

However, if further testing is desired after the primary screening tests, Wintrobe et al disclose 'confirmatory' tests which may be carried out on the blood samples (See Fig. 33-7 (Pg. 1066)). Among the confirmatory tests are a test for fibrinogen level (which reads on what Applicants call a test for fibrinogen), tests for FDP (fibrin-fibrinogen degradation products) (soluble fibrin monomers are FDPs, thus this test is considered to read on what Applicants call a test for soluble fibrin monomers), and tests for platelet aggregation and adhesion (both of which read on Applicants test for platelet activation). It is submitted these tests read on the fibrinogen test, soluble fibrin monomer test, and platelet activation tests required in dependent claims 72, 74-76, 79, and 81-87. Fig. 33-7 (pg 1066) also provides guidance on interpreting the results of these tests to arrive at further diagnosis. As before, disclosure of interpreting abnormal results from the fibrinogen test, FDP test and platelet activation test to arrive at a diagnosis is considered to read on the step of 'using the blood tests to assist in diagnosing the subject with one or more conditions'. Therefore the reference anticipates the claimed subject matter.

Claims 70-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorensen et al (Thromb Res, 1992).

Sorensen et al is concerned with testing the coagulation response level in blood following trauma and/or surgery.

Initially it is noted that conditions which cause a low coagulation response in blood were long known in the art; therefore the step of 'identifying' such conditions is inherently satisfied based on the state of the art. Such knowledge, inherent to the skilled artisan, reads on the step of 'identifying conditions that cause a low coagulation response in blood'. Furthermore, it is noted that blood tests which can identify low coagulation response in blood were also long known in the art; however Sorensen et al do specifically disclose several blood tests which can identify coagulation response levels in blood, including low coagulation response levels (See Pg. 480). Disclosure of such blood tests is considered to

read on the step of 'providing different blood tests that are each for identifying low coagulation response in blood'.

For their study, Sorensen et al obtain blood samples from multiple patients, and submitted the blood samples to prothrombin fragment 1 and 2 test, thrombin-antithrombin III complex test, fibrin monomer test, and fibrin-fibrinogen degradation product tests (See Pg. 680). Results were obtained and observed from the tests, and are presented in Fig 5 (Pg. 482). Performing the tests and providing the results is considered to read on the steps of 'providing a blood sample from one or more patients, performing each of the different blood tests on the blood sample, obtaining a result from each of the tests and observing the results'.

Sorensen et al report elevated levels of prothrombin fragment 1 and 2, thrombin/antithrombin, fibrin degradation products, and fibrinogen degradation products were present the day of trauma, and levels decreased 1 day post-admission (See Pg. 481). Therefore, because the blood tests did not reveal low coagulation response levels, the patients were not diagnosed with a condition that causes a low coagulation response in blood. It is noted the claims only require the information obtained from the tests to 'assist' in diagnosis; therefore, because Sorensen et al did not identify low coagulation response, the information did 'assist' in diagnosis, as it steers one away from a diagnosis of conditions that cause a low coagulation response in blood. Therefore the reference anticipates the claimed subject matter.

(10) Response to Argument

(i) Rejection over Wintrobe et al

With regards to the rejection of claims 70-72, 74-79 and 81-87 over Wintrobe et al under 35 USC 102(b), Applicants have argued that Wintrobe et al is concerned with the study of hemostasis, blood coagulation and blood clotting defects, and particularly sets forth steps and tests to be performed on a bleeding patient to determine the coagulation defects the bleeding patient may have. Applicants argue

that, in contrast to Wintrobe et al, their claimed method is not directed to stopping bleeding or the study of blood coagulation. The only specific portion of Wintrobe et al to which Applicants point, is Table 33-3, which discloses the four primary screening tests; Applicants argue these primary screening tests are not tests for identifying low level activation of the coagulation response in blood, and the results of these tests are not capable of being used to assist in diagnosis of the subject with a condition which causes a low level activation of the coagulation response in blood.

It is noted Applicants have reiterated the same argument in response to each independent claim; thus the following response is applicable to all arguments: It is submitted that Applicants have still not particularly pointed out the patentable novelty which they feel the claims present in view of the state of the art, as disclosed by Wintrobe et al.

Applicants appear to argue that Wintrobe et al fail to identify conditions which cause a low coagulation response in blood; however, it is submitted that this step may be considered a mental step, such conditions which cause low coagulation response levels in blood were known in the art, and furthermore are clearly set forth by Wintrobe et al in at least Tables 33-2 and 33-3.

Applicants also appear to argue that Wintrobe et al does not identify and carry out blood tests which identify low coagulation response levels in blood, and further argue that the four primary screening tests (platelet count, bleeding time, plasma prothrombin time, and partial thromboplastin time (Table 33-3)) are not examples of blood tests which can identify low coagulation response in blood; however, it is submitted that these four primary blood tests, along with the other blood tests disclosed by Wintrobe et al (including tests for fibrinogen levels, platelet activation levels and fibrin-fibrinogen degradation product levels) are, indeed, each standard tests for assaying the coagulation response in blood. It is further noted that fibrinogen levels, platelet activation levels, and soluble fibrin monomer levels (a fibrin-fibrinogen degradation product), are among the tests which Applicants claim as being blood tests that identify low level activation of the coagulation response in blood. Thus, each of the tests disclosed by Wintrobe et al

are standard blood tests used to assay levels of various clotting factors in blood, the skilled artisan will recognize that the levels of clotting factors directly effects the coagulation response level in blood; thus the tests are appropriate to identify low coagulation response levels in blood. Wintrobe et al provide specific guidance on how to interpret each of these tests, to determine which clotting factor is low in the patient (resulting in low coagulation response (i.e. bleeding patients, the subjects of Wintrobe et al)) and then to identify the probable etiology of the bleeding disorder.

The current claims are extremely broad, they are directed to a diagnostic method, which only involves performing known tests on blood samples, and then observing if there are any abnormal values within the blood test results; as such, the more specific diagnostic steps of Wintrobe et al do read on the claimed methods. Therefore, the rejection over Wintrobe et al is believed to still be proper.

(ii) Rejection over Sorensen et al

With regards to the rejection of claims 70-87 over Sorensen et al under 35 USC 102(b), Applicants have argued that Sorensen et al is directed to methods of monitoring activation of coagulation in patients who have suffered trauma, which they feel is divergent from the intended purpose of the claimed method, which is to ex vivo diagnostic method, and as such, the obtained results are different from Applicants invention. Applicants submit that, because of the different intent of Sorensen et al, all inherency arguments must fail. It is further noted that Applicants remark the factors observed by Sorensen et al are not genetic or metabolic procoagulant factors capable of indicating a hereditary propensity for hypercoagulation [*sic*] in a blood sample.

It is noted Applicants have reiterated the same argument in response to each independent claim; thus the following response is applicable to all arguments: It is submitted that the rejections of record are not intended to be inherency rejections, as the claimed method does not require a specific outcome, thus

that outcome would not need to be considered an inherent result; rather, it is submitted that the steps of Sorensen et al, clearly read on the steps of the claimed method.

While Applicants argue that Sorensen et al has a different intent that the instant method, it is submitted that the fact that Sorensen et al is directed to studying coagulation response after trauma is irrelevant. The claimed method does not limit the patient population to subjects suspected of having a hereditary propensity for hypocoagulation in blood samples (low coagulation response in blood would be a *hypo*coagulation state); thus the claimed method is not limited in such a way that it precludes the method from being carried out on trauma patients for the monitoring of coagulation response. The claimed method requires only that conditions which cause a low coagulation response in blood be identified, blood samples be taken from any subjects, subjected to blood tests suitable for detecting low coagulation response in blood, and *if* abnormal results are found in two or more tests, then the test results to *assist* in diagnosis of a condition marked by low coagulation response in blood. In the instant case, as set forth above in the rejection of record, the step of identifying conditions which cause a low coagulation response in blood is considered to be a mental step, as such conditions were known in the art, thus 'identification' of such conditions merely requires identification from the knowledge available to one of ordinary skill in the art. Sorensen et al clearly obtains blood samples and subjects them to the same tests currently claimed as 'tests that are each for identifying low level activation of the coagulation response in blood', it is noted the claimed tests are assays for levels of various coagulation factors in blood, therefore they will reveal both low coagulation response, and high coagulation response in blood. The results of the blood tests were obtained, observed and interpreted by Sorensen et al; the fact that the tests did not reveal low coagulation response levels does 'assist' in diagnosing the subject with a condition marked by low coagulation response in blood, as it rules out such conditions. It is again reiterated that the claimed method only requires the results to 'assist' in diagnosis, by providing a negative result, the method of Sorensen et al is considered to assist in diagnosis.

It is further noted that the method is not limited to diagnosing patients having a propensity towards genetic or hereditary hypocoagulation disorders; therefore Applicants' arguments that none of the tests performed by Sorensen et al are appropriate to identify such disorders is considered to be directed to limitations not in the presently examined claims. However, it is further noted that the tests performed by Sorensen et al are the same as those claimed by Applicants; thus the tests of Sorensen et al have the same potential to detect genetic or hereditary hypocoagulation disorders as in the currently claimed method.

Therefore the rejection of record over Sorensen et al is still believed to be proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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